**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF NEW YORK**

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| **CHAZ HISCOCK,** | § | |
| **an individual,** | § | |
| | § | |
| ***Plaintiff*,** | § | |
| | § | **CAUSE NO. _____** |
| **vs.** | § | |
| | § | |
| **ARGON MEDICAL DEVICES, INC.,** | § | |
| **REX MEDICAL, INC., d/b/a** | § | |
| **REX MEDICAL, L.P. and REX** | § | |
| **MEDICAL, L.P.** | § | **JURY TRIAL DEMANDED** |
| | § | |
| **Defendants.** | § | |

**COMPLAINT**

Plaintiff Chaz Hiscock, by and through his undersigned attorney, hereby sues Defendants Argon Medical Devices, Inc., Rex Medical, Inc., d/b/a Rex Medical, L.P, and Rex Medical, L.P., and alleges as follows:

**PARTIES**

1. Plaintiff Chaz Hiscock ("Plaintiff") at all times relevant to this action resided in, continues to reside in, and is a citizen of, Niagara County in the State of New York.

2. Defendant Argon Medical Devices, Inc. is a Delaware corporation that maintains its corporate headquarters and principal place of business in Collin County, Texas at 5151 Headquarters Drive, Suite 201, Plano, Texas. At all times relevant to this action, Argon has held the exclusive global rights to market and distribute the Option Retrievable Inferior Vena Cava Filter and/or Option Retrievable Inferior Vena Cava Filter, implantable devices used in the

prevention of Pulmonary Embolism (PE). On January 5, 2016, Argon completed the acquisition the Option Retrievable Inferior Vena Cava Filter from Rex Medical. Argon Medical Devices, Inc has been served with process and no further service is requested at this time. Argon Medical Devices, Inc. may be served with process by delivering a Summons with a copy of this Complaint attached thereto, to its registered agent, Cogency Global, Inc., 1601 Elm Street, Suite 4360, Dallas, Texas 75201. Argon Medical Devices, Inc., has conducted business in and derived substantial revenue from sales of its products, including the Defendants' IVC filters, in New York.

3. Defendant Rex Medical, Inc. d/b/a Rex Medical, L.P. is a Pennsylvania corporation is the general partner of Defendant Rex Medical, L.P. Defendant Rex Medical, Inc.'s principal place of business is located at 555 North Lane, Suite 5035, Conshohoken, Montgomery County, Pennsylvania 19428. At all times relevant to this action, Rex Medical, Inc. d/b/a Rex Medical, L.P. designed, developed, manufactured, and marketed the Option Retrievable Inferior Vena Cava Filter ("the IVC Filter") and Option Elite Retrievable Inferior Vena Cava Filter, devices represented to be used in the prevention of Pulmonary Embolism (PE), implanted in patients throughout the United States. Rex Medical, Inc., d/b/a Rex Medical, L.P. may be served with process by delivering a Summons with a copy of this Complaint attached thereto, via certified mail, return receipt requested, to its general partner Rex Medical, Inc., by serving William W. Gardner, President of Rex Medical, Inc. at 1100 E. Hector Street, Suite 245, Conshohoken, Montgomery County, Pennsylvania 19428.

4. Defendant Rex Medical, L.P., a partnership organized under the laws of the State of Pennsylvania with its principal place of business located 555 E. North Lane, Suite 5035, Conshohoken, Montgomery County, Pennsylvania 19428. Rex Medical, L.P. may be served with

process by delivering a Summons with a copy of this Complaint attached thereto, via certified mail, return receipt requested, to its general partner Rex Medical, Inc., by serving William W. Gardner, President of Rex Medical, Inc. at 1100 E. Hector Street, Suite 245, Conshohoken, Montgomery County, Pennsylvania 19428. Defendant Rex Medical, Inc. is the parent company, and according to the Certificate of Limited Partnership filed with the Pennsylvania Department of State on February 29, 1996, the only general partner of Defendant Rex Medical, L.P. There are no limited partners identified in the filings obtained from the Pennsylvania Department of State.

5. Defendant Argon Medical Devices, Inc. shall be referred to herein as "Argon."

6. Defendants Rex Medical, Inc. d/b/a Rex Medical, L.P. and Rex Medical, L.P. shall be referred to herein individually by name or jointly as the "Rex Defendants."

7. At all times alleged herein, the Rex Defendants include and included any and all parent companies, subsidiaries, affiliates, divisions, franchises, partners, joint venturers, and organizational units of any kind, their predecessors, successors, and assigns and their officers, directors, employees, agents, representatives, and any and all other persons acting on their behalf.

8. At all times herein mentioned, each of the Rex Defendants was the agent, servant, partner, predecessors in interest, and joint venturer of each other and were at all times operating and acting with the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

9. At all times herein mentioned, Argon was the agent, servant, partner, predecessor in interest, and joint venturer of the Rex Defendants and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, joint enterprise, and/or joint venture.

10. At all times relevant to this cause of action, Argon and the Rex Defendants were conducting, and continue to conduct, business throughout the United States, including the State of New York. At all times relevant to this cause of action, Argon and the Rex Defendants maintained, and continue to maintain, significant, systematic, and continuous contacts with the State of New York. Argon and the Rex Defendants develop, manufacture, sell, and distribute medical devices for use in various applications including vascular surgical products throughout the State of New York, the United States, and around the world, including the New York City borough of Queens. Argon's and the Rex Defendants' products include the Option Vena Cava Filter, which is used for the prevention of recurrent pulmonary embolism via placement in the vena cava.

11. Upon information and belief, Argon and the Rex Defendants, each and all, expected or should have expected their acts to have consequence within the United States of America and the State of New York, and derived substantial revenue from interstate commerce within the United States and the State of New York.

## JURISDICTION AND VENUE

12. Personal jurisdiction is proper pursuant to N.Y. § 302 (2012). Argon and the Rex Defendants have conducted and continue to conduct substantial and systematic business activities related to their IVC filters, including the Option™ Vena Cava Filter (hereinafter "Option filter") at issue in this case, in this jurisdiction. Such activities include, but are not limited to: (a) sales of IVC filters, including the Option filter at issue in this case, in this jurisdiction; (b) hiring, training, and deploying employees, including managers and sales representatives, in this jurisdiction; (c) advertising and marketing of their IVC filters, including the Option filter at issue in this case, in this jurisdiction; (d) maintenance of company files and equipment relating to the Option filter at

issue in this case, in this jurisdiction; (e) payment of employee salaries in this jurisdiction; and (f) maintenance of a website directed to all states, including New York. Argon and the Rex Defendants committed tortious acts within the State of New York. Argon and the Rex Defendants also caused injury to persons or property within the State of New York arising out of acts or omissions by Argon and the Rex Defendants outside this state at or about the time of the Plaintiff's injury; while Argon and the Rex Defendants were engaged in solicitation or service activities within the State of New York; and/or while products, materials, or things processed, serviced, or manufactured by Argon and the Rex Defendants were used or consumed within New York in the ordinary course of commerce, trade, or use.

13. There is complete diversity between the parties and the amount in controversy exceeds $75,000 exclusive of interest and costs. *See* 28 U.S.C. § 1332.

14. Venue is properly laid pursuant to 28 U.S.C. § 1391(b)(2) and (d), as Argon and the Rex Defendants' Option filter was marketed, sold, implanted, and failed in New York City borough of Queens, New York, and the Defendants are corporations subject to personal jurisdiction in the district.

15. Plaintiff's claims in this action are brought solely under state law. Plaintiff does not herein bring, assert, or allege, either expressly or impliedly, any causes of action arising under any federal law, statute, regulation, or provision. Thus, there is no federal jurisdiction in this action on the basis of a federal question under 28 U.S.C. § 1331.

## ALTERNATIVE ALLEGATIONS

16. To the extent any allegation herein is inconsistent with any other allegation, such inconsistent allegations are pleaded in the alternative pursuant to Fed. R. Civ. P. 8(d)(3).

## GENERAL FACTUAL ALLEGATIONS

17. Plaintiff brings this case for serious, life-threatening injuries he suffered, and will continue to suffer, as a result of Argon's and the Rex Defendants' surgically implanted medical device, the Option filter, that was implanted at Mercy Hospital of Buffalo, Buffalo, New York on April 30, 2018.

18. Argon and the Rex Defendants design, research, develop, manufacture, test, market, advertise, promote, distribute, and/or sell products such as IVC filters that are marketed and sold as a temporary/retrievable device to prevent, among other things, recurrent pulmonary embolism via placement in the vena cava. One such product is the Option Vena Cava Filter.

19. The Defendants sought Food and Drug Administration ("FDA") clearance to market the Option filter and/or its components under Section 510(k) of the Medical Device Amendment.

20. On or about June 4, 2009, the Rex Defendants obtained FDA clearance to market the Option filter device and/or its components under Section 510(k) of the Medical Device Amendment.

21. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device. The device is then cleared by the FDA under Section 510(k). The Defendants claimed that Argon Option filter was substantially equivalent to the Option IVC filter.

22. An IVC filter, like the Option Filter, is a device designed to filter blood clots (called "thrombi") that would otherwise travel from the lower portions of the body to the heart and lungs.

IVC filters may be designed to be implanted, either temporarily or permanently, within the vena cava.

23. The inferior vena cava is a vein that returns blood to the heart from the lower portion of the body. In certain people, and for various reasons, thrombi travel from vessels in the legs and pelvis, through the vena cava into the lungs. Often these thrombi develop in the deep leg veins. The thrombi are called "deep vein thrombosis" or DVT. Once the thrombi reach the lungs, they are considered "pulmonary emboli" or PE.

24. An IVC filter, like the Option filter, is ostensibly designed to prevent thromboembolic events by filtering or preventing blood clots/thrombi from traveling to the heart and/or lungs.

25. The Option filter was designed, manufactured marketed and sold as a retrievable filter. The Rex Defendants represented that the Option filter was be based on the Bard Recovery filter, Bard Recovery G2 filter, the Gunther Tulip filter, the Cordis TrapEase Vena Cava filter and the Cordis OptEase Vena Cava filter.

26. The Option filter consists of shape memory nitinol struts emanating from a central location which is represented to be designed for clot capture.

27. On April 30, 2018, Plaintiff was implanted with an Argon Option filter at Mercy Hospital of Buffalo, in Buffalo, NY.

28. On August 23, 2018, Plaintiff underwent a failed complex percutaneous retrieval attempt at Vascular Associates of WNY in Orchard Park, New York. Multiply retrieval attempts were made, including use of snare, balloons, and magic torque wire. All were unsuccessful.

29. On August 29, 2018, Plaintiff underwent another failed complex percutaneous retrieval attempt at Mercy Hospital of Buffalo, Buffalo, New York. Again, multiply retrieval attempts were made including use of snares, wires, balloons, and alligator forceps. All were unsuccessful.

30. Plaintiff's injury was inherently undiscoverable or objectively verifiable such that, despite Plaintiff's reasonable diligence, he was unable to discover his injury until on or after August 23, 2018.

31. Plaintiff is at risk for future progressive perforations and potential fractures of the Option filter, which could further injure adjacent organs and blood vessels. Plaintiff faces numerous health risks, including the risk of death. Plaintiff will require ongoing medical care and monitoring for the rest of his life. It is unlikely that the filter can be retrieved by any means other than an open surgical procedure.

32. At all times relevant hereto, the Option filter was widely advertised and promoted by Argon, as the exclusive sales agent for the Option filters, and the Rex Defendants as a safe and effective treatment for prevention of recurrent pulmonary embolism via placement in the vena cava.

33. At all times relevant hereto, Argon, as the exclusive sales agent for the Option filter, and the Rex Defendants knew the Option filter was defective and knew that the defect was attributable to the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

34. Argon, as the exclusive sales agent for the Option filter, and the Rex Defendants failed to disclose to physicians, patients, or Plaintiff that its Option filter was subject to tilting,

embedment, breakage, and migration or the appropriate degree of risk of perforation and damage to the vena cava wall.

35. At all times relevant hereto, Argon, as the exclusive sales agent for the Option filter, and the Rex Defendants continued to promote the Option filter as safe and effective even though the clinical trials that had been performed were not adequate to support long- or short-term efficacy.

36. Argon, as the exclusive sales agent for the Option filter, and the Rex Defendants concealed the known risks and failed to warn of known or scientifically knowable dangers and risks associated with the Option filter, as aforesaid.

37. The failure of the Option filter is attributable in part to the fact that it suffers from a design defect causing it to be unable to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

38. At all times relevant hereto, Argon, as the exclusive sales agent for the Option filter, and the Rex Defendants failed to provide sufficient warnings and instructions that would have put Plaintiff and the general public on notice of the dangers and adverse effects caused by implantation of the Option filter, including, but not limited to, the design's failure to withstand the normal anatomical and physiological loading cycles exerted *in vivo*.

39. The Option filter was designed, manufactured, distributed, sold, and/or supplied by the Rex Defendants, and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of the Rex Defendants' knowledge of the product's failure and serious adverse events.

40. The Option filter was marketed, distributed, sold, and/or supplied by Argon and was marketed while defective due to the inadequate warnings, instructions, labeling, and/or inadequate testing in light of Argon's knowledge of the product's failure and serious adverse events

41. At all times relevant hereto, the officers and/or directors of Argon and the Rex Defendants named herein participated in, authorized, and/or directed the production and promotion of the aforementioned products when they knew or should have known of the hazardous and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by Plaintiff.

42. The IVC filter at issue was designed, manufactured, assembled, processed, labeled, marketed, distributed, and sold by the Rex Medical Defendants in the United States after receiving 510k clearance from the United States Food and Drug Administration.

43. The IVC filter at issue was labeled, marketed, distributed, and sold by Argon in the United States after the Rex Medical Defendants received 510k clearance from the United States Food and Drug Administration

44. As stated in the 510k application summary of June 2, 2009, the Option Vena Cava Filter is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava, as was the subsequently cleared Option Elite.

45. Prior to Plaintiff being implanted with the device at issue, Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants knew and should have known that the device was defective and unreasonably dangerous for, inter alia, the following reasons:

a. The Rex Medical Defendants failed to conduct sufficient clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants each knew and/or should have known that the Option Filter had a high rate of embedment, fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Both Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants knew and/or should have known that such failures exposed patients to serious injuries, including death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device.

c. Upon information and belief, Argon, as the exclusive sales agent for the Option and Option Elite Filters and the Rex Medical Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

d. Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants each knew and should have known that these risks for the Option Vena Cava Filter were and are substantially higher than other similar devices.

e. Further, the Rex Medical Defendants each knew and/or should have known that the Vena Cava Filter contained conditions, which Argon and the Rex Medical Defendants each did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

f. Despite being aware of these risks, Argon and the Rex Medical Defendants, and each of them, misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

g. Even as the Rex Medical Defendants designed, marketed and sold what they alleged to be a device that specifically reduced these risks of the Filter, they nonetheless failed to issue a recall of the Filter or otherwise notify consumers that a safer device was available.

h. Even as Argon marketed and sold what it alleged to be a device that specifically reduced the risks of the Filter, it nonetheless failed notify consumers that a safer device was available.

## INFERIOR VENA CAVA FILTERS GENERALLY

46. IVC filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

47. An IVC filter is a device that is ostensibly designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

48. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present risks to human health and can result in death.

49. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

50. The first IVC filter was introduced in the later 1960's. Since then, the market has been supplemented with all types and designs of filters offered by many different manufacturers.

51. Over the years, concern developed within the medical community (and was shared by IVC filter manufacturers) that an IVC filter should be designed and manufactured in a manner to enable retrieval of the device from the body.

52. As stated above, IVC filters have been on the market for decades. All IVC filters are only cleared for use by the FDA for prevention of recurrent PE in patients at risk for pulmonary embolism and where anticoagulation therapy has failed or is contraindicated. In 2003, however an outburst in off-label promotion and use began with the introduction of IVC filters that were cleared for both permanent use and optional retrieval.

53. From 2002 through 2003, manufacturers of IVC filters raced against each other to bring the first IVC filter to the marked with the added indication of optional retrieval. This added feature was intended to provide physicians the option to retrieve the filter after the risk of clots subsided. In 2003, the FDA cleared three different filters for a retrieval indication – the OptEase filter by Cordis and J&J, the Recovery filter by C.R. Bard, Inc., and the Gunther Tulip filter by Cook Medical, Inc.

54. There is no evidence that IVC filters are effective in preventing pulmonary embolism (the very condition that the products were indicated to prevent). There is also evidence that IVC filters expose patients to substantial safety hazards. For example, an October 2015 article published in The Annals of Surgery concerning trauma patients inserted with IVC filters concluded that IVC filters were not effective in preventing pulmonary emboli and instead actually caused thrombi to occur.

55. Comparing results of over 30,000 trauma patients who had not received IVC filters with those who had received them, the Annals of surgery study published in its alarming results:

a. Almost twice the percentage of patients with IVC filters in the study died compared to those who had not received them;

b. Over five times the relative number of patients with IVC filters developed DVTs;

c. Over four times the relative percentage of patients with filters developed thromboemboli; and

d. Over twice the percentage of patients developed a pulmonary embolus – the very condition Defendants represented to the FDA, physicians, and the public that its Option filters and Option Elite filters were designed to prevent.

56. Other studies also have revealed that these devices suffer common failure modes such as inter alia, tilt, migration, perforation, thrombosis, and fracture, all of which can cause serious injury or death. These studies have shown that there is no reliable or objective evidence establishing that IVC filters are effective and that these devices suffer common failure modes, all of which can cause serious injury or death. Thus, the current state of scientific and medical evidence indicates that IVC filters, including Option and Option Elite filters are not only ineffective, but are themselves a health hazard.

**THE OPTION AND OPTION ELITE FILTERS**

57. Defendant Rex Medical, bypassing the more onerous FDA's approval process for new devices, obtained "clearance" under Section 510(k) of the Medical Amendments Act to the Federal Food, Drug and Cosmetic Act to market the Option filter and Option Elite filter as permanent filters with the option for removal by claiming that they were substantially similar in respect to safety, design, and materials as IVC filters already available on the market.

58. Section 510(k) permits the marketing of medical devices if the device is substantially equivalent to other legally marketed predicate devices without formal review for the safety or efficacy of said device. The FDA explained the difference between the 510(k) process and the more rigorous "premarket approval" ("PMA") process in its amicus brief filed with the Third Circuit in *Horn v. Thoratec, Corp*., which the court quoted from:

59. A manufacture can obtain an FDA finding of 'substantial equivalence' by submitting a premarket notification to the agency in accordance with section 510(k) of the [Food, Drug, and Cosmetic Act]. 21 U.S.C. § 360(k). A device found to have 'substantial equivalence' to a predicate device is said to be 'cleared' by FDA (as opposed to 'approved' by the agency under a PMA). 376 F.3d 163, 167 (3d Cir. 2004) (emphasis in original). A premarket notification submitted under 510(k) is thus entirely different from the PMA process, which requires data sufficient to demonstrate that the medical device is safe and effective.

60. In *Medtronic, Inc. v. Lohr*, the U.S. Supreme Court similarly described the 510(k) process, observing as follows:

> If the FDA concludes on the basis of the [manufacturer's] § 510(k) notification that the device is "substantially equivalent" to a pre-existing device, it can be marketed without further regulatory analysis. […] The § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete PMA review, the 510(k) review is completed in average of 20 hours. […] As one commentator noted: "The attraction of substantial equivalence to manufacturers is clear. Section 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed quickly.

518 U.S. 470, 478-79 (1996) (quoting Adler, The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction, 43 Food Drug Cosm. L.J. 511, 516 (1988)).

61. Pursuant to *Wyeth v. Levine*, 555 U.S. 555 (2009), once a product is cleared "the manufacturer remains under an obligation to investigate and report any adverse events associated with the drug…and must periodically submit any new information that may affect the FDA's previous conclusions about the safety, effectiveness, or labeling…" This obligation extends to post-market monitoring of adverse events/complaints.

62. In or around April 2009, the Rex Medical Defendants sought clearance from the FDA through the 510(k) process to market the Option filter as a permanent filter, with the option for removal, for prevention of recurrent pulmonary embolism via placement in the vena cava. The Rex Medical Defendants cited six predicate devices as being substantially equivalent to the Option filter, and represented that the design, material, components, fundamental technology, and intended use of the Option filter was substantially similar to the predicate devices.

63. The Option filter is made of Nitinol – a nickel titanium alloy. The filter utilizes a conical shape design for the capture of blood clots and/or emboli. This design consists of consists of six expandable and collapsible struts which flare out from a central apex. The Option filter has a total of six anchoring hooks – three small hooks and three large hooks. The anchoring hooks, located distally at the caudal portion of each strut for fixation to the vena cava wall, are ostensibly designed to prevent movement.

64. In or around June 2009, Defendant Rex Medical obtained clearance from the FDA through the 510(k) process to market the Option filter as a permanent filter, with the option for removal, for the prevention of recurrent pulmonary embolism via placement in the vena cava.

65. After obtaining clearance from the FDA through the 510(k) process to market the Option filter, Rex Medical Defendants, and each of them, researched, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold the Option filters to health care professionals and the consuming public.

66. In or around September 2013, the Rex Medical Defendants sought clearance through the 510(k) process to market the Option Elite filter for the same indicated uses as the Option filter.

67. The Rex Medical Defendants cited only one predicate device – the Rex Medical Defendants' own Option filter – as being substantially equivalent to the Option Elite filter.

68. The Rex Medical Defendants represented in its 510(k) application to the FDA (and, hence, to the medical community, including Plaintiff's physicians) that the Option Elite filter contained the same or similar materials, technological characteristics, principle of operation, and design and was substantially equivalent in terms of safety and efficacy as the Option filter.

69. The Option Elite filter is made of Nitinol – a nickel titanium alloy. The filter utilizes a conical shape design, similar to that of the Option filter, for the capture of blood clots and/or emboli. This design consists of consists of six expandable and collapsible struts which flare out from a central apex. The Option Elite filter has a total of six small anchoring hooks – as compared to its sole predicate device, the Option filter, which has three small and three large anchoring hooks. These six small anchoring hooks, located distally at the caudal portion of each strut for fixation to the vena cava wall, are ostensibly designed to prevent movement.

70. In or around December 2013, the Rex Medical Defendants obtained clearance from the FDA through the 510(k) process to market the Option Elite filter as a permanent filter, with the option for removal, for the prevention of recurrent pulmonary embolism via placement in the vena cava.

71. After obtaining clearance from the FDA through the 510(k) process to market the Option Elite filter, the Rex Medical Defendants, and each of them, researched, developed, tested, designed, set specifications for, licensed, manufactured, prepared, compounded, assembled, packaged, processed, labeled, marketed, promoted, distributed, and/or sold their Option Elite filters to Plaintiff, Plaintiff's prescribing health care professionals, and the consuming public.

72. The designs for the Option filter and Option Elite filter both suffer similar design and manufacturing flaws making them defective and unreasonably dangerous. The Option and Option Elite filters are designed in such a way that when exposed to expected and reasonably foreseeable in-vivo conditions, the filters will, inter alia, migrate, perforate internal organs and vasculature, fracture, and lead to the formation of thromboembolism and PE.

73. Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants, and each of them, represented that the self-centering design of the Option filter and Option Elite filter allows accurate, predictable placement, and that its struts reduce the risk of tilting and migration, while in reality the filters regularly tilt, migrate, and become embedded in the vena cava wall. The anchoring mechanism of the Option and Option Elite filters are, thus, insufficient to prevent tilting and migrations post-placement.

74. The configuration of the Option and Option Elite filters renders them prothrombotic. This means that the Option filters and Option Elite filters actually lead to the formation of thromboembolism and PE – the exact condition these filters are meant to prevent.

75. The fact the Rex Medical Defendants allowed these devices to proceed to market indicates that they failed to establish and maintain an appropriate Quality System concerning design and risk analysis.

76. A medical device manufacturer must, at a minimum, undertake such research and testing to understand the anatomy of where a device will be implanted and understand the forces the device may be exposed to once in the human body. This design input must then be used to determine the minimum safety requirements or attributes the device must have to meet user needs. In the case of an IVC filter, user needs include a device that will capture blood clots of sufficient

size to cause harmful consequences and that will not fracture, migrate, tilt, perforate the vena cava, or be prothrombotic. The Rex Medical Defendants failed to undertake any such efforts in these regards.

77. Prior to bringing a product to market, a medical device manufacturer must also conduct sufficient testing under real world or simulated use conditions to ensure that the device will meet user needs even when exposed to reasonably foreseeable worst-case conditions. The Rex Medical Defendants failed to adequately establish and maintain such policies, procedures or protocols with respect to the Option filter and Option Elite filter.

78. On March 15, 2011 Argon Medical Devices, Inc. entered into a definitive license agreement with Rex Medical, LP for exclusive rights to market and distribute the Option Retrievable Inferior Vena Cava Filter. On information and belief this exclusive licensing agreement was amended to include the Option Elite filter once the Rex Medical Defendants obtained 510(k) clearance for that device

79. Once placed on the market, the Rex Medical Defendants' post-market surveillance system revealed, or should have revealed, to Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants that the Option and Option Elite filters were unreasonably dangerous and substantially more prone to fail or malfunction and cause great bodily harm and/or death to patients compared to other available treatment options.

80. MAUDE (Manufacturer and User Facility Device Experience) is a database maintained by the FDA to house medical device reports submitted by mandatory reporters (such as manufacturers and device user facilities) and voluntary reporters (such as health care providers and patients). Shortly after market release for the Option and Option Elite filters, respectively,

Argon, , as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants began receiving large numbers of adverse event reports ("AER") from health care providers reporting that the Option and Option Elite filters were fracturing post-implantation and that fractured pieces and/or the entire device were migrating to other areas of the body, including the spine, heart and lungs. Argon, as the exclusive sales agent for the Option and Option Elite Filters and the Rex Medical Defendants, and each of them, also received large numbers of AERs reporting that the Option and Option Elite filters were found to have excessively tilted, perforated the vena cava, or caused thrombosis or stenosis of the vena cava post-implantation. These device malfunctions were often associated with reports of inability to retrieve the filter and/or severe patient injuries, including but not limited to, the following: death; hemorrhage; cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart); cardiac arrhythmia and other symptoms similar to myocardial infraction; severe and persistent pain; perforations of tissue, vessels and organs; chronic DVT; PE, thrombotic issues; and compartment syndrome.

81. These failures and resulting injuries are attributable, in part, to the fact that the Option and Option Elite IVC filters, including the Option filter implanted into Plaintiff, were unable to withstand the normal anatomical and physiological loading cycles exerted in vivo.

82. As a minimum safety requirement, medical device manufacturers must establish and maintain post-market procedures to timely identify the cause of device failures and other quality problems and to take adequate corrective action to prevent the recurrence of these problems. The Rex Medical Defendants, however, failed to identify or acknowledge these device failures or determine their causes. The Rex Medical Defendants also failed to take timely and

adequate remedial measures to correct known design and manufacturing defects with the Option and Option Elite filters.

83. Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants engaged in a marketing scheme whereby they concealed material risk information and promoted unproven benefits of the Option and Option Elite filters in order to induce health care providers, including the Plaintiff's prescribing and implanting physicians, to purchase and use the Option and Option Elite filters.

84. The information distributed by Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants to Plaintiff's physicians was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, and commercial media containing material representations, instructions for use and direct communications from sales representatives, inter alia, as set forth in further detail herein.

85. The physicians that prescribed the Option filter to Plaintiff reviewed marketing and labeling materials regarding this filter, which were created and distributed by Argon and the Rex Medical Defendants. These marketing and labeling materials and the direct representations from Argon's sales representatives to Plaintiff's physicians misrepresented and concealed the risks and benefits of the Option and Option Elite filters, including the Option filter implanted in the Plaintiff.

86. Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants each represented that the Option and Option Elite filters were safe and effective – more so than other available IVC filters; however, Argon and the Rex Medical Defendants each were well aware that there was not, and never has been, any reliable basis for

such claims or any objective evidence establishing that the Option and Option Elite filters improve patient outcomes at all. In fact, the available evidence indicates otherwise.

87. Argon, as the exclusive sales agent for the Option and Option Elite Filter sand at the specific instruction of the Rex Defendants, and the Rex Medical Defendants also represented to Plaintiff's prescribing and implanting physicians that the design of the Option and Option Elite filters, including the Option filter implanted in the Plaintiff, would eliminate the risk that pieces of the filters could perforate the vena cava, that the devices could tilt, or that fractures could occur and migrate throughout the body. The medical literature and the hundreds of malfunctions and associated adverse events reported to Argon and Rex Medical Defendants, alone, have proven these claims to be false.

88. The marketing and labeling materials created and/or distributed by Argon, as the exclusive sales agent for the Option Filter and Option Elite Filter, and the Rex Medical Defendants to Plaintiff's physicians also intentionally concealed the risks associated with the Option and Option Elite filters, including, but not limited to, tilt, migration, fracture, perforation, thrombosis, the prothrombotic nature of the devices, or that these failures were known to be causing severe injuries and death, or the rate at which these events were occurring. These materials also purposefully omitted information known to both Argon and the Rex Medical Defendants that the Option filters and Option Elite filters, including the Option filter implanted in the Plaintiff, posed higher risk of these aforementioned failures and adverse events than other IVC filters.

89. Had the Rex Medical Defendants not engaged in a marketing scheme directed to Plaintiff's physicians, as described herein, Plaintiff's physicians would not have prescribed the Option filter to Plaintiff. Additionally, Plaintiff's physicians, at a minimum, would have passed

complete and accurate risk benefit information on to Plaintiff as part of the informed consent process, and Plaintiff would not have consented to the use of an Option filter.

90. Had Argon, as the exclusive sales agent for the Option Filter and Option Elite Filters and at the specific instruction of the Rex Defendants, not engaged in a marketing scheme directed to Plaintiff's physicians, as described herein, Plaintiff's physicians would not have prescribed the Option filter to Plaintiff. Additionally, Plaintiff's physicians, at a minimum, would have passed complete and accurate risk benefit information on to Plaintiff as part of the informed consent process, and Plaintiff would not have consented to the use of an Option filter.

91. For the forgoing reasons, the Option and Option Elite filters, including the Option filter implanted in the Plaintiff, were, and remain, extremely dangerous, defective and unsafe for use by the general public for the filters' intended purposes.

92. Prior to the date on which Plaintiff was implanted with the Option filter, the Rex Defendants knew that the Option and Option Elite filters, including the Option filter implanted in the Plaintiff, were defective and extremely dangerous and unsafe for use by the public for their intended purposes. The wrongful conduct described herein was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of the Rex Medical Defendants.

93. The Rex Medical Defendants nonetheless failed to take appropriate action to cure the nature of the defects inherent in the Option and Option Elite filters or to appropriately warn users of these devices or their physicians of such dangerous characteristics.

94. Prior to the date on which Plaintiff was implanted with the Option filter, Argon knew that the Option and Option Elite filters, including the Option filter implanted in the Plaintiff,

were defective and extremely dangerous and unsafe for use by the public for their intended purposes. The wrongful conduct described herein was done with the advance knowledge, authorization, and/or ratification of an officer, director, and/or managing agent of Argon.

95. Argon nonetheless failed to take appropriate action to appropriately warn users of these devices or their physicians of such dangerous characteristics.

96. The six predicate devices that the Rex Medical Defendant contends are substantially similar to its Option Vena Cava Filter are the following:

a. Boston Scientific Greenfield Vena Cava Filter determined substantially equivalent on January 6, 1997 (also K964284; (K955396; K951508);

b. Cordis Trapease Vena Cava Filter (K000062) determined substantially equivalent on July 7, 2000;

c. Cordis Optease Vena Cava Filter (K023116) determined substantially equivalent on October 18, 2002;

d. Bard Recovery Vena Cava Filter (K022236) determined substantially equivalent on November 27, 2002;

e. Gunther-Tulip Vena Cava Filter Set (K032426) determined substantially equivalent on October 31, 2003; and

f. Recovery G2 Filter (K073090) determined substantially equivalent on January 15, 2008.

97. Upon information and belief, both Argon, as the exclusive sales agent for the Option and Option Elite Filters, and the Rex Medical Defendants engaged in marketing and promotional activities that were not only false and misleading as to safety and efficacy, but were also designed to illegally expand the use of their IVC filters for off-label indications, i.e., indications for which the products had not been cleared by the FDA, without scientific proof of

the devices safety and efficacy so as to increase sales and profits at the expense of the safety, health, and well-being of the public, including the Plaintiff.

98. Upon information and belief, Option and Option Elite Filters, including the Option filter implanted in the Plaintiff, are adulterated pursuant to 21 U.S.C. § 351 because, among other things, they failed to meet established performance standards, and/or the methods, facilities, or controls used for their manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. § 351.

99. Upon information and belief, the Option and Option Elite filters, including the Option filter implanted in the Plaintiff, are misbranded because, among other things, it is dangerous to health when used in the manner indicated, recommended or suggested in the labeling thereof. *See* 21 U.S.C. § 352.

100. Upon information and belief, the Option and Option Elite filters, including the Option filter implanted in the Plaintiff, are adulterated pursuant to 21 U.S.C. § 351 because the Rex Medical Defendants failed to establish and maintain CGMP for their Filter System in accordance with 21 CFR § 820 *et seq.,* as set forth above.

101. Upon information and belief, the Rex Medical Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their filters. As a result of the Rex Medical Defendants' failure to establish and maintain CGMP as set forth above, Option and Option Elite filters, including the Option filter implanted in the Plaintiff, were defective and failed, resulting in injuries to the Plaintiff. If the Rex Medical Defendants had

complied with the federal requirements regarding CGMP, the Option filter would have been manufactured properly such that the filters would not have resulted in injuries to the Plaintiffs.

**DISCOVERY RULE, ESTOPPEL, AND FRAUDULENT CONCEALMENT**

102. Plaintiff incorporates by reference the factual portion of this Complaint as if fully set forth herein and additionally, or in the alternative, if same be necessary, allege as follows.

103. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury, and the tortuous nature of the wrongdoing that caused the injury.

104. Despite diligent investigation by Plaintiff into the cause of Plaintiff's injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages and their relationship to the Plaintiff's filter and Argon and/or the Rex Medical Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statute of limitations for filing the Plaintiff's claims. Therefore, under appropriate application of the discovery rule, the Plaintiff's suit was filed well within the applicable statutory limitations period.

105. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by both Argon and the Rex Medical Defendants when they had a duty to disclose those facts. Both Argon and the Rex Medical Defendants' purposeful and fraudulent acts of concealment have kept each Plaintiff ignorant of vital information essential to the pursuit of that Plaintiff's claims, without any fault or lack of diligence on the Plaintiff's part, for the purpose of obtaining delay on the Plaintiff's part in filing on his

causes of action. Both Argon and the Rex Medical Defendants' fraudulent concealment did result in such delay.

106. Both Argon and the Rex Medical Defendants are estopped from relying on the statute of limitations defense because Argon and the Rex Medical Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the Option filter.

107. Both Argon and the Rex Medical Defendants were and remain under a continuing duty to disclose the true character, quality and nature of the device that was implanted in the Plaintiff but instead they concealed them. Argon and the Rex Medical Defendants' conduct, jointly and severally, as described in this complaint, amounts to conduct purposely committed, which they must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of the Plaintiff.

## CORPORATE/VICARIOUS LIABILITY

108. At all times herein mentioned, Argon and Rex Defendants were agents, servants, partners, aiders and abettors, co-conspirators, and/or joint venturers, and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy, and/or joint venture and rendered substantial assistance and encouragement to each other, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

109. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between Argon and Rex Defendants, such that any individuality and separateness between them have ceased and they are alter egos. Adherence to the fiction of the separate

existence of Argon and Rex Defendants as entities distinct from each other will permit an abuse of the corporate privilege, would sanction a fraud, and/or would promote injustice.

110. At all times herein mentioned, Argon and Rex Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, advertising for sale, and/or selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

111. At all times herein mentioned, the officers and/or directors of Argon and Rex Defendants named herein participated in, authorized, and/or directed the production, marketing, promotion, and sale of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

## COUNT I
## NEGLIGENCE

112. At all times relevant to this cause of action, Rex Defendants were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the Option IVC filter, including Option filter at issue in this case.

113. Argon and Rex Defendants designed, manufactured, marketed, inspected, labeled, promoted, distributed, and sold Option filter that was implanted into Plaintiff.

114. Rex Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution, and sale of the Option IVC filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

115. Argon had a duty to exercise reasonable and prudent care in the marketing, labeling, promotion, distribution, and sale of the Option IVC filter so as to avoid exposing others to foreseeable and unreasonable risks of harm

116. Argon and Rex Defendants knew or should have known that the Option filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

117. At the time of manufacture and sale of the Option filter, the Rex Defendants knew or reasonably should have known that the Option filter:

a. Was designed and manufactured in a way so as to present an unreasonable risk of tilt and or embedment;

b. Was designed and manufactured so as to present an unreasonable risk perforation and/or damage to the vena cava wall;

c. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

d. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

e. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

f. Was designed and manufactured in a way that increased the potential for recurrent thrombosis and clot formation.

118. The Rex Defendants breached their duty of reasonable care and were negligent in:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Option Filter, specifically its incidents of tilt, embedment, fracture, migration, perforation, recurrent thrombosis and other failures;

b. Unreasonably and carelessly designed, manufactured, Advertised, marketed and sold a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly designed, manufactured, advertised, marketed and sold a product that presented a risk of harm to Plaintiff and others similarly situated in that it was prone to fail.

d. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

e. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

f. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

g. Failing to use reasonable care to warn or instruct, including pre- and post-sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Option Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

h. Failing to perform reasonable pre and post-market testing of the Option Filter to determine whether or not the product was safe for its intended use;

i. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Option Filter;

j. Advertising, marketing and recommending the use of the Option Filter, while concealing and failing to disclose or warn of the dangers known by the Rex Defendants to be connected with and inherent in the use of the Option Filter;

k. Representing that the Option Filter was safe for its intended use when in fact, the Rex Defendants knew and should have known the product was not safe for its intended purpose;

l. Continuing manufacture and sale of the Option Filter with the knowledge that said product was dangerous and not reasonably safe and failing to comply with the F.D.A. good manufacturing regulations;

m. Failing to use reasonable and prudent care in the design, research, manufacture, and development of the Option Filter so as to avoid the risk of serious harm associated with the use of the Option Filter;

n. Advertising, marketing, promoting and selling Option Filter for uses other than as approved and indicated in the product's label;

o. Failing to establish an adequate quality assurance program used in the manufacturing of the Option Filter;

p. Failing to establish and maintain an adequate post-market surveillance program, including, but not limited to, employing unqualified, inadequately trained, and inadequately supervised individuals to review, adjudicate, and report safety complaints concerning the Option filter to the FDA.

119. At the time of sale of the Option filter, Argon knew or reasonably should have known that the Option filter:

a. Was designed and manufactured in a way so as to present an unreasonable risk of tilt and or embedment;

b. Was designed and manufactured so as to present an unreasonable risk perforation and/or damage to the vena cava wall;

c. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

d. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

e. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body; and/or

f. Was designed and manufactured in a way that increased the potential for recurrent thrombosis and clot formation.

120. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

121. Argon breached its duty of reasonable care and was negligent in:

a. Unreasonably and carelessly failing to properly warn of the dangers and risks of harm associated with the Option Filter, specifically its incidents of tilt, embedment, fracture, migration, perforation, recurrent thrombosis and other failures;

b. Unreasonably and carelessly advertised, marketed and sold a product that was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body;

c. Unreasonably and carelessly advertised, marketed and sold a product that presented a risk of harm to Plaintiff and others similarly situated in that it was prone to fail.

d. Failing to use reasonable care to warn or instruct, including pre and post sale, Plaintiff, Plaintiff's physicians, or the general health care community about the Option Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to provide adequate instructions, guidelines, and safety precautions, including pre and post sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the Option Filter;

f. Advertising, marketing and recommending the use of the Option Filter, while concealing and failing to disclose or warn of the dangers known by Argon to be connected with and inherent in the use of the Option Filter;

g. Representing that the Option Filter was safe for its intended use when in fact, Argon knew and should have known the product was not safe for its intended purpose;

h. Continuing advertise, market and sell the Option Filter with the knowledge that said product was dangerous and not reasonably safe and failing to comply with the F.D.A. good manufacturing regulations; and,

i. Advertising, marketing, promoting and selling Option Filter for uses other than as approved

122. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the aforementioned acts and omissions.

123. As a direct and proximate result of Argon's and the Rex Defendants' negligence,

as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

**COUNT II**
**STRICT PRODUCTS LIABILITY – FAILURE TO WARN**

124. The Rex Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Option filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

125. At the Rex Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, the Rex Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use.

126. The Rex Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the Option filter, which was implanted in Plaintiff, that the filter posed a significant risk of device failure (tilt, embedment, perforation of the vena cava wall, fracture, migration and recurrent thrombosis) and resulting serious injuries.

127. Argon, marketed, labeled, distributed, and sold the Option filter, including the one implanted into Plaintiff, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

128. At the time Argon marketed, labeled, distributed, and sold the device into the stream of commerce, Argon knew or should have known the device presented an unreasonable

danger to users of the product when put to its intended and reasonably anticipated use.

129. Argon knew or should have known at the time it labeled, distributed and sold the Option filter, which was implanted in Plaintiff, that the filter posed a significant risk of device failure (tilt, embedment, perforation of the vena cava wall, fracture, migration and recurrent thrombosis) and resulting serious injuries.

130. Argon and the Rex Defendants each had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the safe and proper use of the device. Argon and the Rex Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff.

131. Argon and the Rex Defendants each failed to adequately warn of material facts regarding the safety and efficacy of the Option filter, and further failed to adequately provide instructions on the safe and proper use of the device. These failures rendered the Option filter unreasonably dangerous to Plaintiff.

132. No health care provider, including Plaintiff's, or patient, including the Plaintiff, would have used the Option filter in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

133. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

134. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

135. Therefore, the Option filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling, and/or instructions accompanying the product.

136. The Option filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed, and sold by Argon and the Rex Defendants.

137. As a direct and proximate result of Argon's and the Rex Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

**COUNT III**
**STRICT PRODUCTS LIABILITY – DESIGN DEFECT**

138. At all times relevant to this action, the Rex Defendants developed, tested, designed, manufactured, inspected, marketed, labeled, promoted, distributed, and sold into the stream of commerce the Option filter, including the one implanted in Plaintiff.

139. At all times relevant to this action, Argon marketed, labeled, promoted, distributed, and sold into the stream of commerce the Option filter, including the one implanted in Plaintiff.

140. The Option filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Argon's and the Rex Defendants' possession. In the alternative, any changes that were made to Option filter implanted in Plaintiff were reasonably foreseeable to Argon and the Rex Defendants.

141. The Option filter implanted in Plaintiff was defective in design in the following ways:

a. It was not reasonably safe, that is, it was so likely to be harmful to persons that a reasonable person who had actual knowledge of its potential for producing injury would conclude that is which not have been marketed in that condition;

b. It failed to perform as safely as persons who ordinarily use the product would have expected at the time of use; and

c. Its risks of harm exceeded its claimed benefits.

142. Argon and the Rex Defendants each knew that safer alternative designs were available, which would have prevented or significantly reduced the risk of the injury presented by Option filter. Further, it was economically and technologically feasible at the time the filter left the control of Argon and the Rex the Defendants to prevent or reduce the risk of such a dangerous event by application of existing, or reasonably achievable, scientific knowledge.

143. Plaintiff and Plaintiff's health care providers used the Option filter in a manner that was reasonably foreseeable to Argon and the Rex Defendants.

144. Neither Plaintiff, nor Plaintiff's health care providers, could have, by the exercise of reasonable care, discovered the device's defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

145. The defective design of the Option filter was a producing cause of Plaintiff's injuries.

146. As a result of the Option filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

**COUNT IV**
**STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT**

147. The Rex Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the Option filter that was implanted into Plaintiff.

148. Argon marketed, labeled, distributed, and sold the Option filter that was implanted into Plaintiff.

149. The Option filter implanted into Plaintiff contained a condition or conditions that rendered it not reasonably safe, which Argon and the Rex Defendants did not intend, at the time it left Argon and/or the Rex Defendants' control and possession.

150. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Argon and the Rex Defendants.

151. As a result of this condition or these conditions, the Option filter injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

152. As a direct and proximate result of the Option filter's manufacturing defects, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

**COUNT V**
**BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY**
**AND FITNESS FOR A PARTCULAR PURPOSE**

153. Argon and the Rex Defendants each breached implied warranties under the New York Uniform Commercial Code, N.Y. § 2-314.

154. At all times relevant to this action, the Rex Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold distributed into the stream of commerce the Option IVC filter, including the one implanted in Plaintiff, for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

155. At all times relevant to this action, Argon advertised, promoted, marketed, sold distributed into the stream of commerce the Option IVC filter, including the one implanted in Plaintiff, for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels

156. At the time and place of sale, distribution, and supply of the Option filter to Plaintiff by way of Plaintiff's health care providers and medical facilities, Argon and the Rex Defendants each expressly represented and warranted, by labeling materials submitted with the product, that the Option filter was safe and effective for its intended and reasonably foreseeable use.

157. Argon and the Rex Defendants each knew of the intended and reasonably foreseeable use of the Option filter at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

158. At the time and place of sale, distribution, and supply of the Option filter to Plaintiff by way of Plaintiff's health care providers and medical facilities, Argon as the exclusive sales agent for the Option Filter and at the specific instruction of the Rex Defendants expressly

represented and warranted, by labeling materials submitted with the product, that the Option filter was safe and effective for its intended and reasonably foreseeable use as a permanent IVC filter.

159. Argon and the Rex Defendants each impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the Option filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

160. At the time the Option filter left Argon and the Rex Defendants' possession, and at the time of Plaintiff's purchase from Argon and the Rex Defendants, the Option filter was not in a merchantable condition, in that:

a. It was designed in such a manner so as to be prone to an unreasonably high incident of tilt, embedment, fracture, perforation of vessels and organs, and/or migration;

b. It was designed in such a manner so as to result in an unreasonably high incident of injury to the organs including the vena cava of its purchaser; and

c. It was manufactured in such a manner so that the Option filter would weaken and fail.

161. Additionally, implied warranties were breached as follows:

a. Argon and the Rex Defendants each failed to provide the warnings or instructions and/or adequate warnings or instructions which a manufacturer exercising reasonable care would have provided concerning the risks, in light of the likelihood that the Option filter would cause harm;

b. The Rex Defendants manufactured and/or sold the Option filter and that filter did not conform to representations made by the Rex Defendants when it left their control.

c. Argon sold the Option filter and that filter did not conform to representations made by Argon when it left their control;

d. The Rex Defendants manufactured and/or sold the Option filter, a device that was more dangerous than an ordinary consumer would expect when used in an

intended or reasonably foreseeable manner, and the foreseeable risks associated with the Option filter design or formulation exceeded the benefits associated with that design. These defects existed at the time the product left Argon's and the Rex Defendants' control; and

e. Argon sold the Option filter, a device that was more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner, and the foreseeable risks associated with the Option filter design or formulation exceeded the benefits associated with that design. These defects existed at the time the product left Argon's and the Rex Defendants' control;

162. Further, Argon's and the Rex Defendants' marketing of the Option filter was false and/or misleading.

163. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of the Rex Defendants as the designers, researchers and manufacturers of the product, as to whether the Option filter was of merchantable quality, safe and fit for its intended use and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Option filter was manufactured and sold.

164. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Argon as the marketer, distributor and seller of the product, as to whether the Option filter was of merchantable quality, safe and fit for its intended use and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the Option filter was manufactured and sold

165. Argon and the Rex Defendants placed the Option filter into the stream of commerce in a defective and unreasonably unsafe condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the Option filter was manufactured and sold.

166. Argon and Rex Defendants each breached their implied warranties because the Option filter was not fit for its intended use and purpose.

167. As a direct and proximate result of the Option filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

**COUNT VI**
**BREACH OF EXPRESS WARRANTY**

168. Argon and the Rex Defendants breached express warranties under the New York Uniform Commercial Code, N.Y. § 2-314.

169. Plaintiff, through his medical providers, purchased the Option filter from Argon and the Rex Defendants.

170. At the time and place of sale, distribution, and supply of the Option filter to Plaintiff, Argon and the Rex Defendants each expressly represented and warranted that the Option filter was safe and used sales aids, among other things, comparing the lack of complaints in the FDA's MAUDE database for its filter as compared to that of other IVC filter manufacturers, while knowing that the lack of data in the MAUDE database was inherently flawed and an unreliable source of information to demonstrate the safety of Option Filter. Argon made this representation at the specific instruction of the Rex Defendants.

171. At the time and place of advertising, marketing, sale, distribution, and supply of the Option filter to Plaintiff, Argon expressly represented and warranted that the Option filter was safe and effective for use a permanent filter with the option to be retrieved for preventing pulmonary

embolisms, even though the clinical trials that had been performed were not adequate to support long- or short-term efficacy and there is no evidence that IVC filters are effective in preventing pulmonary embolism (the very condition that the products were indicated to prevent). There is also evidence that IVC filters expose patients to substantial safety hazards. Argon made these representations at the specific instruction of the Rex Defendants.

172. Plaintiff, through his attending physicians, relied on these representations in determining which IVC filter to use for implantation in Plaintiff.

173. At the time of Plaintiff's purchase from Argon and the Rex Defendants, the Option filter was not safe, in that:

a. It was prone to an unreasonably high incident of tilt, embedment, fracture, perforation of vessels and organs, and/or migration;

b. It was prone to an unreasonably high incident of injury to the organs including the vena cava of its purchaser;

c. It was insufficient in strength or structural integrity to withstand the foreseeable use of normal placement within the human body, thus, the Option filter would weaken and fail during implantation;

d. It was not safe for use as a permanent IVC filter.

174. The Option filter was unfit and unsafe for use by users as it posed an unreasonable and extreme risk of injury to persons using said products, and accordingly, Argon and the Rex Defendants breached their expressed warranties associated with the product.

175. As a direct and proximate result of the Option filter's defects, as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, economic loss, disability, and other losses, in an amount to be determined at trial.

## COUNT VII
## NEGLIGENT MISREPRESENTATION

176. At all times relevant to this cause, and as detailed above, Argon and the Rex Defendants each negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information, concerning the Option filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the Option filter;

b. The efficacy of the Option filter;

c. The rate of failure of the Option filter; and

d. The approved uses of the Option filter.

177. The information distributed by Argon and the Rex Defendants to the public, the medical community, and Plaintiff's health care providers was in the form of reports, press releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading and contained omissions and concealment of the truth about the dangers of the use of the Option filter. These materials included instructions for use and warning document that was included in the package of the Option filter that was implanted in Plaintiff.

178. Argon and the Rex Defendants each failed to exercise reasonable care or competence in communicating the information. Argon and the Rex Defendants each made the foregoing misrepresentations knowing that they were false or without reasonable basis.

179. Argon's and the Rex Defendants' intent and purpose in making these

representations was: (1) to deceive and defraud the public and the medical community, including Plaintiff's health care providers; (2) to gain the confidence of the public and the medical community, including Plaintiff's health care providers; (3) to falsely assure them of the quality of the Option filter and its fitness for use; and (4) to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the Option filter.

180. The foregoing representations and omissions by Argon and the Rex Defendants were in fact false. The Option filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the Option filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff suffered.

181. In reliance upon the false and negligent misrepresentations and omissions made by Argon and the Rex Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the Option filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

182. Argon and the Rex Defendants each knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Argon and the Rex Defendants and would not have prescribed and implanted same if the true facts regarding the device had not been concealed and misrepresented by Defendants.

183. Argon and Rex Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in

the form of dangerous injuries and damages to persons implanted with the Option filter.

184. At the time Argon and Rex Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the Option filter, Plaintiff and Plaintiff's health care providers were unaware of Argon's and the Rex Defendants' negligent misrepresentations and omissions.

185. Plaintiff, Plaintiff's health care providers, and general medical community reasonably relied upon the foregoing misrepresentations and omissions made by Argon and the Rex Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the Option filter.

186. Plaintiff's health care providers and Plaintiff's agents' reliance on the foregoing misrepresentations and omissions by the Rex and Argon Defendants was the direct and proximate cause of Plaintiff's injuries as described herein. As a result of the Rex and Argon Defendants' misrepresentations and omissions, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

## PUNITIVE DAMAGES CLAIM

187. Plaintiff is entitled to an award of punitive and exemplary damages based upon Argon and the Rex Defendants intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, as their complete and total disregard for the public safety and welfare.

188. Argon and the Rex Defendants each had knowledge of, and were in possession of evidence demonstrating that, the Option filter was defective, unreasonably dangerous, and had a substantially higher failure rate than did other similar devices on the market. Despite their

knowledge, Argon and the Rex Defendants each failed to, among other purposeful acts, inform or warn Plaintiff, Plaintiff's agents, or his health care providers of the dangers, establish and maintain an adequate quality and post-market surveillance system, and recall Option filter from the market.

189. As a direct, proximate, and legal result of Argon and the Rex Defendants acts and omissions as described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, pain and suffering, mental anguish, medical expenses, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

## PRAYER FOR DAMAGES

**WHEREFORE**, Plaintiff, Chaz Hiscock, prays for relief on the entire complaint, as follows:

a. Judgment to be entered against Argon and the Rex Defendants, jointly and/or severally, on all causes of action of this Complaint, including but not limited to:

   1. Physical pain and suffering in the past and which, in reasonable probability, he will continue to suffer in the future;

   2. Physical impairment and incapacity in the past and which, in reasonable probability, he will continue to suffer in the future;

   3. Mental anguish in the past and which, in reasonable probability, he will sustain in the future;

   4. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical probability, the reasonable medical expenses he will need in the future; and,

   6. Punitive damages.

b. Plaintiff be awarded full, fair, and complete recovery for all claims and causes of action relevant to this action;

c. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of New York as authorized by law on the judgments entered in Plaintiff's behalf; and,

d. Such other relief the court deems just and proper.

**DEMAND FOR JURY TRIAL**

Plaintiff hereby demands trial by jury on all issues.

Dated: August 23, 2021.

Respectfully Submitted,

*/s/ Laura J. Baughman*
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